TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	11/3/2020
Department:	Core Lab	**Due Date:**	11/30/2020
		Implementation:	**11/10/2020**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Millipore (AFS – Analyzer Feed System), Siemens Dimension® EXL GEC.C279 v1

AFS-16(D) Maintenance Log and System Readings AG.F539.2

Description of change(s):

SOP: New SOP describing the updated Millipore system and maintenance. Expectations include

- daily maintenance is performed by night shift
- be familiar with the new log and how to obtain the readings
- know where to find the operator's manual (It's on the G drive and on a USB card located in a pocket on the Millipore system)
- be familiar with the SOP

FORM: Updated to match SOP

The SOP and Form will be implemented on November 10, 2020

Document your compliance with this training update by taking the quiz in the MTS system.

Adventist HealthCare

Germantown Emergency Center

AFS-16(D) Maintenance Log and System Readings

Month/Year _____ S/N _____

1. Turn on Millipore water and let drain into a container until the tank begins to fill (tank level bars will be flashing).
2. Turn off the spigot.
3. Press the two opposing arrows ◄►at the same time for two seconds to access the operation parameters.
4. Press the check mark to view reading and ► to scroll through.
5. Press the index icon to return to Ready Mode.
6. Remember to record the vacuum pressure on the right side of the Millipore.

Perform daily:		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
1	Product Quality (10-15 MΩ-cm)																															
2(d2)	Feed Conductivity																															
3(d3)	Feed Temp (< 35ºC)																															
4(d4)	RO Pump Pressure																															
5(d5)	% Rejection (>92%)																															
6(d6)	Permeate Conductivity																															
7	Product Vacuum in Hg																															
	Tech																															

Perform monthly:		
Collect water for Bacterial content	Date:	Tech:
Bacterial content (≤ 10 CFU/mL)	Result:	

Perform as needed:		
Replace Chlorine Tablet	Date:	Tech:
pH Cleaning of RO Cartridge	Date:	Tech:
Change Progard	Date:	Tech:
Change Tank Vent Filter	Date:	Tech:
Change Q-gard	Date:	Tech:
Change Final Filter (BioPak C)	Date:	Tech:

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review:

Non-Technical SOP

Title	**Millipore (AFS – Analyzer Feed System), Siemens Dimension® EXL**
Prepared by	Valerie Rose Date: 10/15/2020
Owner	Robert SanLuis Date: 10/15/2020

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

TABLE OF CONTENTS

1. PURPOSE

The purpose of this procedure is to outline the use and maintenance of the Millipore AFS Water Purification System. The Millipore AFS Water Purification System will be utilized as the Analyzer Feeder System for Dimension EXL analyzers.

2. SCOPE

This procedure applies to Laboratory staff who operate the Dimension EXL analyzers.

3. RESPONSIBILITY

Laboratory staff who operate the Dimension EXL analyzer, prepare reagents, utilize water or culture the system are responsible for monitoring and/or maintenance of the Millipore system.

4. DEFINITIONS

Clinical Laboratory Reagent Water (CLRW) – water that meets the requirements of the Clinical and Laboratory Standards Institute (CLSI).

AFS – Analyzer Feed System; a water purification system that produces CLSI Type I Product Water directly from potable tap water. The system combines Reverse Osmosis (RO) and Ion Exchange technology to accomplish this. The product water then feeds the analyzer directly, without any extra user interaction. The FAS system is designed to produce CLSI Type I quality water.

5. PROCEDURE

5.1 Operating principle and status

An Analyzer Feed System ("AFS®") is a water system designed to automatically feed an analyzer. The AFS® D (or Degasser) includes a degassing device which is used to remove air from the product water delivered to the analyzer.

As a summary, the system purifies tap water using the Progard® Pack and Reverse Osmosis (RO). A tank and pump are used to store and distribute the product water to the Analyzer. A sensor is used to determine if the Analyzer needs water. This water is further purified by ion exchange before going to the Analyzer.

Understanding the terminology of operating status:

DISTRIBUTION -- The system has detected that the analyzer needs water. Thus the distribution part of the system is producing water and sends that water to the analyzer.

RECIRCULATION -- The system is periodically recirculating water in the distribution portion of the system but no water is being delivered to the analyzer.

TANK FILLING -- The distribution tank is being filled by RO Water. A sensor starts and stops this mode.

FLUSH -- A periodic flush of the RO portion of the system is done. This refreshes the water in this part of the system if they are not being used to produce water.

RINSING -- A sensor has determined that the RO portion needs to rinse itself before sending water to the tank.

SANITIZATION -- There are different types of sanitization that can be done. See the maintenance section in this document for more information.

CLEANING -- An acid or base cleaning can be done. A packaged chemical is available for this type of cleaning. See the maintenance section in this document for more information.

5.2 General Information

Parameter	CLSI/CAP specification for Type I Water
Maximum bacterial content	< 10 CFU/ml*
Minimum resistivity	10 MΩ-cm**
Maximum silicate level	< 0.05 mg/L
Particulate matter	0.22 micron filter
Organic contaminants	Activated carbon*** or Reverse Osmosis or Distillation
pH	Not specified

*CFU/ml = colony forming units per ml
** MΩ.cm=Megohm.cm compensated to 25° C
*** Not required by CAP

5.3 System Operation

5.3.1 Keypad Usage

The keypad allows you to interface with the system. Changing the software modes, reviewing the system's performance, and initiating maintenance procedures can be done via the keypad.

1 – MODE key – This button is used to switch between different system modes: Standby or maintenance mode, Ready or tank filling mode and Configuration mode.

- From Standby, press twice to go the Ready.
- From Ready, press once to go to Standby.

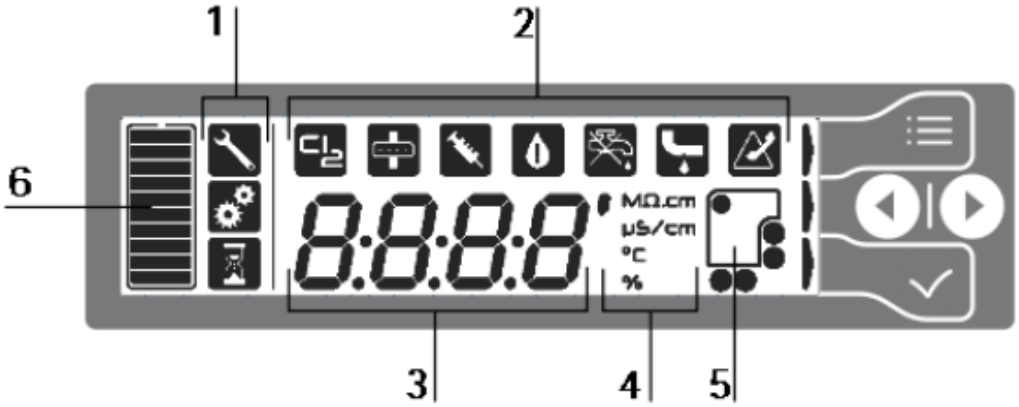
2 – LEFT or RIGHT key – These buttons are used to navigate in the user interface software. They are also used to change configuration or set point values.

3 – VALIDATE key – This button is used to confirm a change or an action required by the water system. It is also used to save any changes made in configuration.

4 – HELP INDICATOR icon – There are up to 3 of these icons on the display depending upon the software mode. These indicators are here to tell the user which keypad button is available and active.

5.3.2 Display Icons

Know how to interpret each icon displayed. These are displayed below.



1 – System status indications are:

a.  Maintence or tool: the system is in Standby or maintenance can be started.

b.  Configuration or gears: configuration parameters such as set points can be changed.

c.  Process or hourglass: the system is busy. No action can be done.

2 – Warning maintenance or alarm are displayed to indicate that maintenance action is required or that a parameter is out of range.

3 – Values area is used to display water quality measures, software menu and configuration values, or error code numbers.

4 – Units of measurement

5 – Consumables status icons are used to indicate that a maintenance action is required.

6 – Tank filling is represented by the top bar. When the top bar is blinking, the system fills the tank. When it's not blinking, the tank full level is reached.

5.3.3 View Operation Parameters

In Ready or Tank filling, press and hold 2 seconds on left and right arrows  to access operation parameters.

d1	Tap water feed conductivity value can be displayed by pressing ✓. Press ✓ to go back to d1 view.	235 µS/cm
d2	RO feed water conductivity value can be displayed by pressing ✓. Press ✓ to go back to d2 view.	283 µS/cm
d3	RO water temperature value can be displayed by pressing ✓. Press ✓ to go back to d3 view.	16.8 °C
d4	RO pump pressure value can be displayed by pressing ✓. Press ✓ to go back to d4 view.	4.5
d5	RO % rejection value can be displayed by pressing ✓. Press ✓ to go back to d5 view.	98.8 %
d6	RO permeate water conductivity value can be displayed by pressing ✓. Press ✓ to go back to d6 view.	12.5 µS/cm

5.3.4 Sanitization and Cleaning

A chlorine tablet is periodically used to reduce or remove a layer of bio film on the feed water side of the RO membrane. It may also become necessary to remove any build up layer of mineral scale or organic material, which is done with a pH cleaner.

Refer to section 5.3.7 of this document, or to the Maintenance section of the User Manual, for a complete description of both cycles.

5.3.5 Error Messages and Basic Troubleshooting

An error code is always displayed with the  icon and can be displayed in two different ways:

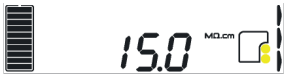
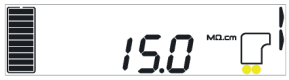
Yellow display alert error: 

Red display alarm error: 

Please see the User Manual for the list of error codes and basic troubleshooting.

5.3.6 Replacement of Consumables

Table for quick reference for when the consumables should be exchanged:

Consumables names	When to change the Consumables
Progard pack	 When the sytem show this icon, order a new Progard pack. It will be exhausted in 15 days.  When the system displays this yellow alert, replace the Progard pack. It is recommended to replace the Tank Vent filter at this time. It is also recommended to clean the feed water strainer. Additionally, replace the Progard if the system has been turned off for more than 48 hours. System should be powered on and in STANDBY mode when the Progard is replaced.
Tank Vent filter	Replace the Tank Vent filter when the Progard is exchanged.
Q-Gard pack	 When the system displays this icon, order a new Q-Gard. It will be exhausted in 15 days.  When the system displays this yellow alert, replace the Q-Gard.
BioPak C final filter	 When the system displays this icon, order a new final filter. It will be exhausted in 15 days.  When the system displays this yellow alert, replace the final filter.

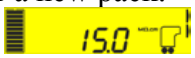
a) Replacing Progard Pack

- When the system shows the icon  order a new pack.
- When the system displays the yellow alert  replace the pack (it is recommended to replace the Tank Vent filter at this time, and to clean the feed water strainer).
- Verify or put the system in Standby by pressing the Mode key 
- To REMOVE the exhausted pack:
    1. Unlock the locking handle by pulling up.

2. Pull out the pack.
   Note: when the pack is removed, a RED color display appears. This is normal. This will go away when a new pack is installed.

- To place a NEW pack:
  1. Remove the new pack from its shipping box. Remove the 2 protective caps from the ports at the top of the pack. Locate the O-ring inside each port to make sure the O-rings are pushed inside against the inner edge of the ports.
  2. Mount the bottom of the pack onto the small hole in the cabinet. Swing the rest of the pack so that the top of the Pack aligns with pack locking handle and the cabinet ports.
  3. Push the top of the pack in place.
  4. Push the pack locking handle down to secure the pack.
     - The new pack is detected.
     - The display prompts you to start a "Progard flush": press  for 1 second.
     - The "Progard flush" lasts 15 minutes.
     - System goes in Tank Filling automatically.

b) Replacing Q-Gard Pack

- When the system shows the icon  order a new pack.
- When the system displays the yellow alert  replace the pack.
- BEFORE replacing the pack, verify the tank is FULL.
- Verify or put the system in Standby by pressing the Mode key 
- To REMOVE the exhausted pack:
  1. Locate the Sampling Port. It is typically located downstream of the final filter. Place a container under to collect any water that will come out when it's opened.
  2. Open the valve. Wait until water stops flowing out.
  3. Detach the tubing from the final filter inlet. Place this tubing end into a drain or sink.
  4. Pull up the locking handle.
  5. Pull out the entire pack.
     Note: when the pack is removed, an alarm appears. This is normal. The alarm will go away when a new pack is installed.
- To place a NEW pack:
  1. Remove the new pack from its shipping box. Remove the 2 protective caps from the ports at the top of the pack. Locate the O-ring inside each port to make sure the O-rings are pushed inside against the inner edge of the ports.
  2. Mount the bottom of the pack onto the small hole in the cabinet. Swing the rest of the pack so that the top of the Pack aligns with pack locking handle and the cabinet ports.
  3. Push the top of the pack in place.
  4. Push the pack locking handle down to secure the pack.
     - The new pack is detected.

- The display prompts you to start a "polisher rinse": press ✓ next for 1 second.
- Wait for 2-3 minutes.
- Put the system in Standby.

5. Reconnect the tubing on the final filter inlet.
6. Close the sampling valve. Press ☰ to put the system in Ready or Tank Filling.

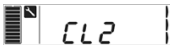
c) Replacing Final Filter

- When the system shows the icon  order a new final filter.
- When the system displays the yellow alert  replace the final filter.
- Before replacing the final filter verify that the tank is at least HALF FULL.
  Note: do not rinse the final filter with a pack that has not been rinsed out.
- To REMOVE the final filter:
  1. Verify or put the system in Standby by pressing ☰.
     - The system displays LF: 01.
  2. Open the sampling valve to remove the pressure in the distribution product line.
  3. Disconnect the final filter from the distribution product line.
  4. Unscrew the fittings from both ends of the filter.
  5. Remove the final filter.
- To place a NEW final filter:
  1. Remove the new filter from its shipping box.
  2. Screw the fittings on both ends.
  3. Connect the new filter on the distribution product line, and open or verify that the sampling valve is opened.
  4. Press ✓ for 1 second to put the system in Tank Filling and to reset the life time.
     - Remove air from the final filter by unscrewing the air vent cap.
     - Close it once it is air purged.
     - The display prompts you to start a final filter rinse: press ✓ next for 1 second.
     - Wait for 2-3 minutes.
     - Put the system in Standby.
  5. Close the sampling valve.

5.3.7 Maintenance

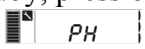
a) Sanitizing RO Membranes with Chlorine

- A chlorine tablet is periodically used to reduce or remove a layer of bio film on the feed water side of the RO membrane.
- When the system shows the yellow alert  , put the system in Standby by pressing ☰
  1. Using the tool, unscrew the sanitation port cap (refer to the Quick Reference Guide for visual aid).

2. Remove the plug and insert one chlorine tablet into the port using proper safety equipment.
3. Screw the plug back into place, making sure the O-ring is in place.
4. To start the CL2 sanitization, press  for 1 second to start CL2 sanitization. You will see this icon 
   - The sanitization lasts 19 minutes, then the system goes into Ready or Tank Filling.

   Note: The sanitization can be cancelled in emergency cases or when started by mistake. Press  during the cycle to abort sanitization.

b) Cleaning RO Membranes with acid/base (pH)

- A pH cleaning should be performed as needed, as it may become necessary to remove any build up layer of mineral scale or organic material. This is done with a pH Cleaner.
- To start the cleaning, make sure the system is in Standby or put the system in Standby by pressing 
  1. Using the tool, unscrew the sanitation port cap (please refer to the Quick Reference Guide for visual aid).
  2. Remove the plug and insert one chlorine tablet into the port.
  3. Screw the plug back into place, making sure the O-ring is in place.
  4. To start the pH cleaning, with the system already in Standby, press on RIGHT arrow  to go past the CL2 icon to this icon 
  5. Press  for 1 second to start pH cleaning.
     - The cleaning lasts 82 minutes.
  6. Once the cleaning is finished, press  to put the system in Standby.
  7. Unscrew the plug and REMOVE the empty pouch from the cleaning port.
  8. Screw the plug back and put the system in Tank Filling by pressing twice.

5.3.7 Monitoring Bacterial Levels in Water

To meet CLSI requirements for the specification of bacteria count, periodic testing is recommended. Bacteria cultures must be performed monthly.

a) To obtain water for culture:
   1) Sanitize the sampling port (upper port with RED cap): remove red cap and wash the port with a 10% bleach solution and then with an alcohol prep pad.
   2) Open the sampling port SLOWLY to avoid being sprayed and let it run for at least 1 minute.
   3) Collect 10 ml of water in a sterile container (urine culture collection cup).
   4) Record collection of water (date/tech code) on the AFS-16(D) Daily Maintenance Log

b) To order and process the culture:
   1) Order via the LIS:
      a. Log in to Sunquest through **Order Entry**

b. For Look up Mode: **HOSP. NO**
c. Hospital number: type **MILL-7** (choose MILLIPORE-SGAH)
d. Enter **Collection date**, **Collection time**, **Receive date, and Receive time**.
e. Order Physician: type **40658**
f. Order Code: type **XH2O** and for
g. SDES: type **WATER**.
h. Label the containers using the LIS accession labels.

2) Prepare for culture at SGMC:
   a. In the LIS, track the order to SGMC using template code GIC.
   b. **Sample must be REFRIGERATED within 2 hours of collection** (stable for 24 hours).
   c. Send to SGMC for FES and subsequent transport to Chantilly for culture.

c) Culture results:
   1) Access and print results from LIS one week after sending.
   2) Record results as CFU/mL on the AFS-16(D) Daily Maintenance Log
   3) Acceptable values are ≤ 10 CFU/mL.
   4) Document corrective action if value is unacceptable:
      a. Collect another sample and re-submit for testing
      b. If repeat test is unacceptable, contact Millipore

5.3.8 Documentation of Maintenance

Complete AFS-16(D) Maintenance Log and System Readings form

6. RELATED DOCUMENTS

AFS-16(D) Maintenance Log and System Readings (AG.F539)

7. REFERENCES

User manual, Millipore, V 4.0, 04/2019. www.millipore.com, www.millipore.com/techservice, www.millipore.com/lab_water
1-888-645-5478

CLSI Document GP40-A4-AMD, Vol.26, No.22 (formerly C03-A4-AMD), Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Standards 4th Edition, 2012

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By

9. ADDENDA

None